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FEB 28 2006

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY DM DEPUTY CLERK

IMMUNOCEPT, LLC, PATRICE ANNE
LEE, AND JAMES REESE MATSON,

Plaintiffs,

v.

FULBRIGHT & JAWORSKI, LLP,

Defendant.

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CAUSE NO. A050A334 SS

**DEFENDANT FULBRIGHT & JAWORSKI, LLP'S RESPONSE TO
PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF JOHN R. KIRK**

COMES NOW, Fulbright & Jaworski, LLP ("Fulbright"), and files this Response to Plaintiffs' Motion to Exclude the Testimony of John R. Kirk and in support thereof, would respectfully show the Court as follows:

I. Introduction

The Plaintiffs' Motion to Exclude the Testimony of John R. Kirk ("Motion") cites several cases and makes some arguments with which Fulbright can agree. At base, the Plaintiffs argue that: (1) there is no black-and-white rule that a patent's preamble language can never limit a claim; and (2) there is no black-and-white rule that a negative limitation can never limit a claim. Fulbright has no quarrel with those propositions. Nor did Mr. Kirk in his testimony and report. Rather, Mr. Kirk reported and testified that, *with respect to the patent at issue in this litigation*, arguing that the '418's preamble language was a limitation or attempting to include a negative limitation would not have been proper means of avoiding the prior art cited by the Patent & Trademark Office's Examiner. To be sure, in limited circumstances, preamble language and

negative limitations *can* limit claims. Mr. Kirk is of the opinion that, under the circumstances presented to Fulbright in 1996, using the preamble or a negative limitation to get around prior art references would have been improper and fruitless.

II. Mr. Kirk rebutted Mr. MacPherson's opinions

Mr. Kirk has expressed his opinions regarding the propriety of the preamble or a negative limitation being used during the '418's prosecution process to differentiate prior art to rebut Plaintiffs' expert Alan MacPherson's suggestion that those tactics would have been preferable to the amendment actually made by Fulbright to the claim language of the '418.

III. Mr. Kirk's opinions regarding the impropriety of relying upon preamble language to distinguish prior art *in this case* have support in the law

The language that the Plaintiffs quote from the *Catalina* case is telling:

In general, a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. Conversely, a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.

Motion, p. 4 (quoting *Catalina Mktg. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal quotations omitted)). Plainly, under some "rare" circumstances, a preamble is limiting, and under most circumstances, it is not. *Catalina*, 289 F.3d at 809. Mr. Kirk has offered his opinion that it is not limiting *in this instance*: "The language . . . appears in the preamble of the claim prior to the transition phrase and body of the claim and thus is merely a statement of purpose for the invention and adds nothing to the step of filtering and thus would not be considered to be a claim limitation." (Motion, Apx. 29, ¶9.) Mr. Kirk did not suggest that preamble language could *never* be limiting, and the Plaintiffs' claim that "Mr. Kirk argues that a claim preamble cannot be limiting" is disingenuous at best. (Motion, p. 4.)

Nor is it true, as the Plaintiffs claim, that "[a] preamble will always be limiting *if the*

applicant argues that it is during prosecution of the patent.” First of all, the Plaintiffs rely upon dicta in a case that was published in 2002 to support Mr. MacPherson’s opinion that Fulbright should have argued that the preamble created a limitation more than *six years earlier* when the “consisting of” amendment was made. Second, the *Catalina* case was an infringement suit, such that the preamble was examined as a possible limitation to be used against the patentee – there is no suggestion that an Examiner would consider an argument *during the prosecution process* that the preamble was a limitation that could be used to avoid prior art. See *In re Morris*, 127 F.3d 1048, 1053-54 (Fed. Cir. 1997) (noting the disparate standards for construing a patent by an Examiner during prosecution and by a court during an infringement suit).

Even in the context of litigation, the Federal Circuit has engaged in a case-by-case determination regarding whether or not preamble language is a limitation. For example, *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, dealt with the following method claim:

A method for reducing hematologic toxicity in a cancer patient undergoing [t]axol treatment comprising parenterally administering to said patient an antineoplastically effective amount of about 135-175 mg/m² taxol over a period of about three hours.

246 F.3d 1368, 1371 (Fed. Cir. 2001). The court in *Bristol-Myers* held that the preamble expression in that claim, “for reducing hematologic toxicity,” was not a limitation, as it merely expressed a purpose of the invention. The court noted that “[t]he steps of the [patented] method are performed in the same way regardless of whether the patient experiences a reduction in hematologic toxicity, and the language of the claim itself strongly suggests the independence of the preamble from the body of the claim.” *Id.* at 1375. Likewise, the steps of hemofiltration are performed in the same way regardless of whether the method is used “for treating a pathophysiological state caused by a toxic mediator-related disease,” and so an argument by Fulbright to the Examiner that the ‘418 preamble should be used as a limitation on the Plaintiffs’

claim would have been inappropriate.

It is unfair to challenge Mr. Kirk's testimony on the basis that there may be other circumstances in which the preamble language of a patent claim may limit the claim. The issue raised by Mr. MacPherson is whether the preamble *in this case* should have been made a limitation on the claim so as to overcome the prior art cited by the Examiner, and there is no sound basis for precluding Mr. Kirk's testimony with respect to that.

IV. Mr. Kirk's opinions regarding the impropriety of using a negative limitation to distinguish prior art *in this case* have support in the law

As with the Plaintiffs' argument regarding limitations based on the preamble, the criticism of Mr. Kirk's opinions regarding use of negative limitations is grounded in a faulty interpretation of those opinions. Again, Mr. Kirk has expressed the opinion that a negative limitation would have been inappropriate during the '418 prosecution; he did not state that a negative limitation would never be permissible.

Plaintiffs correctly quote from Mr. Kirk's testimony, in which he stated that a negative limitation "has to have support in the specification." (Motion, p. 7.) The Plaintiffs then cite to the *Parks* decision's language stating that "lack of literal support does not, in and of itself, establish a *prima facie* case for lack of adequate descriptive support." (Motion, p. 7 (quoting *Ex parte Parks*, 30 U.S.P.Q.2d 1234, 1236 (Bd. Pat. App. & Int. 1994).) But this quote is not in any way inconsistent with Mr. Kirk's opinion in this case – that there must be *some* support, whether literal or implicit, for the negative limitation Mr. MacPherson would put on the Plaintiffs' claims. Mr. Kirk never stated that there must be "literal" support in the specification for a negative limitation. The *Parks* decision states that "it is sufficient [to support a negative limitation] if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." 30 U.S.P.Q.2d at

1236.

Plaintiffs' reliance on *Parks* for the proposition that a negative claim limitation to exclude the addition of heat would have been proper in the '418 patent is not well founded. The PTO Board of Patent Appeals and Interferences determined in that case the addition of a negative limitation reading "such decomposition being conducted in the absence of a catalyst" was held to have been supported by a specification that made no mention of a catalyst, but the facts in that case were quite unusual. The Board found that due to the particular nature of the particular step in question in the claimed process, the discussion of that step in the specification "would seem to cry out for a catalyst if one were used." 30 U.S.P.Q.2d at 1236.

Plaintiffs do not assert, and certainly do not point out, any part of the specification in the '418 patent that "would seem to cry out" for heat, such that the absence of a calling for heat would constitute a disclosure that the inventors regarded the absence of heating as a part of their invention. There is no suggestion in the specification of the '418 patent that persons of ordinary skill in the field of blood filtration would read the patent as describing a method or process that excluded any heating steps, or that the absence of heat was important to the invention. Rather, Plaintiffs' expert Mr. MacPherson seems to contend that if there was no "literal" mention of a heating step in a patent's specification, that a negative limitation was somehow *automatically* justified:

Q. Now what -- have you reviewed the Ex parte Parks case?

A. Yes, I did.

Q. What is your construction of what that case says?

A. It says that: If a fair reading by one skilled in the art of the specification shows that a particular limitation was not contemplated by the disclosure, that you can use the negative limitation in the claim to distinguish.

Q. And what is your opinion of whether the limitation of without heat was -- fit that criteria?

A. I think it did in the '418 patent.

Q. Why?

A. Because there is absolutely no mention of heating, of use of thermofiltration whatsoever. It, in fact, talks about hemofiltering blood with a filter, and basically the description has no reference whatsoever to heating otherwise cooling or otherwise treating the blood in that manner.

(MacPherson Deposition, pp. 221-22.) In fact, the analysis is much more nuanced. A negative limitation on a claim *may* be appropriate in some cases in which the specification – explicitly or inherently – discloses a basis for that limitation. Courts look to whether the negative limitation is a meaningful disclosure or simply a means to obviate prior art references. For example, the *In re Bankowski* case involved the following negative limitation: “an artificial medium containing living bovine kidney cells, but devoid of avian tissue.” 318 F.2d 778, 783 (C.C.P.A. 1963). The court held: “These claims do not appear to us to be objectionable since they *affirmatively specify* the constitution of the culture media.” *Id.* (emphasis added). Similarly, the *In re Duva* case involved claims to a certain compound and a process which included a solution “absent sufficient CN ions to prevent disposition induced by said palladous salt.” The court reversed rejection of the claims: “Here, like *Bankowski*, the claims do not appear to us to be objectionable since they *affirmatively specify* the constitution of the bath and the positive steps required for the claimed process.” 387 F.2d 402, 407, 156 USPQ 90, 94-95 (C.C.P.A. 1967) (emphasis added).

The *Duva* and *Bankowski* cases call for an analysis of whether or not the negative limitations suggested by Mr. MacPherson “affirmatively specify” a part of the Plaintiffs’ invention – and it is highly doubtful that the absence of heat “affirmatively specif[ies]” anything about the Plaintiffs’ process. But now is not the time to determine whether or not a negative limitation could have been used as a matter of law. Two credentialed patent experts in this case have expressed their opinions, and they do not agree whether it was appropriate under the facts of this case. Neither side has argued – nor could they – that a negative limitation is *always* or *never* justified. The Plaintiffs themselves bring this to the Court’s attention in footnote 5 of their

Motion: “The issue of whether the requirement for an adequate written description has been met is a question of fact that is driven by the exigencies of each case.” (Motion p. 7.) Mr. Kirk’s analysis of the relevant case law and its bearing upon the Plaintiffs’ patent is relevant to this factual determination, and there is no basis to exclude his testimony.

V. Mr. Kirk can testify regarding the use of “consisting of”

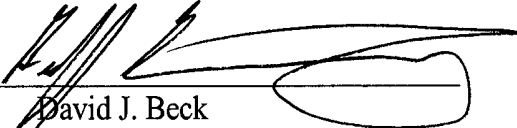
Finally, Plaintiffs are attempting to preclude Mr. Kirk from testifying regarding whether a PTO Examiner would notice the “consisting of” language in an amended claim. The Plaintiffs do not challenge that the “consisting of” language is obvious to someone familiar with the patent prosecution process (in fact, Mr. MacPherson testified to this effect). Contrary to the Plaintiffs’ assertions, Mr. Kirk need not testify as to “the Examiner’s mental state that departs from the written record” to provide such testimony. Rather, the “written record” (the amended claim) and the general understanding of patent counsel (the effect of “consisting of”) support Mr. Kirk’s conclusion that the “consisting of” language played a role in the issuance of the ‘418 patent.

VI. Conclusion and Prayer

Fulbright respectfully requests that Plaintiffs’ Motion to Exclude the Testimony of John R. Kirk be denied in all respects, and that Fulbright be awarded such additional relief to which it may be entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served as shown below on counsel of record on February 27, 2006.

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